

Galapagos announces first dosing with Toledo compound GLPG3970 in psoriasis trial

- TOL2/3 inhibitor most advanced compound in novel target class with dual action in inflammatory diseases
- Patient trials initiated with GLPG3970 in psoriasis, ulcerative colitis, and rheumatoid arthritis
- Toledo class target to be disclosed at Toledo Roundtable on 27 October 2020

Mechelen, Belgium; 29 September 2020, 22.01 CET – Galapagos NV (Euronext & NASDAQ: GLPG) announces dosing of a first patient in their psoriasis trial, one of three patient trials currently recruiting to evaluate efficacy and safety of Toledo compound GLPG3970. Furthermore, Galapagos plans to unveil the novel Toledo target class and share GLPG3970 Phase 1 data at its inaugural Toledo Roundtable to be held virtually on 27 October 2020.

“We are excited by the rapid progress of GLPG3970 in the clinic,” said Dr. Piet Wigerinck, Chief Scientific Officer at Galapagos. “We now have multiple proof of concept studies running in parallel in several autoimmune diseases, and we aim to launch 2 additional Phase 2 studies, in Sjögren’s and systemic lupus erythematosus, early next year, further broadening the scope of the program. We have observed the dual mode of action of GLPG3970 in healthy volunteers, and through these patient trials, we aim to learn quickly whether clinical experience bears out the potential of our Toledo program to become a new paradigm in the treatment of inflammatory diseases.”

CALOSOMA study: Phase 1 trial in psoriasis

The Calosoma Phase 1 trial (NCT04106297) is a double-blind, placebo-controlled study evaluating the safety, tolerability, PK and PD¹ of GLPG3970 single and multiple ascending doses in up to 52 adult healthy male subjects. GLPG3970 will now be investigated for 6 weeks in 25 subjects with moderate to severe psoriasis. The first patient was dosed recently.

SEA TURTLE study: Phase 2 trial in ulcerative colitis

This Phase 2 trial is a double-blind, placebo-controlled study evaluating the efficacy, safety, tolerability, PK and PD of GLPG3970 in up to 30 subjects with moderately to severely active UC. GLPG3970 or a placebo will be administered orally once daily for 6 weeks, with the primary endpoint of change from baseline in total Mayo Clinical Score (MCS).

LADYBUG study: Phase 2 trial in rheumatoid arthritis

This Phase 2 trial is a double-blind, placebo-controlled study evaluating the efficacy, safety, tolerability, PK and PD of GLPG3970 in up to 25 participants with severely active RA and an inadequate response to methotrexate. GLPG3970 or a placebo will be administered orally once-daily for 6 weeks, with the primary endpoint of change from baseline of DAS28 CRP at week 6. Recruitment will take place in Europe.

Toledo Roundtable 27 October 2020

Galapagos cordially invites institutional investors and analysts to attend our inaugural Roundtable dedicated to Toledo. The one-hour Roundtable will be webcast on 27 October 2020, starting at 16.00 CET/9 am ET. Please RSVP to ir@glpg.com.

¹ Pharmacokinetics and pharmacodynamics

About Toledo

“Toledo” is a code name for a novel target class discovered by Galapagos for autoimmune and fibrotic diseases. This Toledo platform delivers small molecule inhibitors of Toledo targets with different selectivity profiles. GLPG3970 has immunomodulatory activity with a dual mode of action characterized by enhanced transcription of anti-inflammatory cytokines and inhibited transcription of pro-inflammatory cytokines. GLPG3970 has shown encouraging preclinical activity in a number of inflammatory diseases, including inflammatory bowel diseases, rheumatoid arthritis, and psoriasis. Galapagos is executing on a broad program to discover and develop multiple series of compounds with different selectivity on Toledo targets, aimed at treating a broad range of autoimmune conditions with still important unmet medical need.

GLPG3970 is an investigational drug and its efficacy and safety have not been established.

For information about clinical trials with GLPG3970: www.clinicaltrials.gov.

About Galapagos

Galapagos (Euronext & NASDAQ: GLPG) discovers and develops small molecule medicines with novel modes of action, three of which show promising patient results and are currently in late-stage development in multiple diseases. The company’s pipeline comprises Phase 3 through to discovery programs in inflammation, fibrosis, osteoarthritis and other indications. Galapagos’ ambition is to become a leading global biopharmaceutical company focused on the discovery, development and commercialization of innovative medicines. More information at www.glp.com.

Contacts

Investors:

Elizabeth Goodwin
VP Investor Relations
+1 781 460 1784

Sofie Van Gijssels
Senior Director Investor Relations
+32 485 19 14 15
ir@glpg.com

Media:

Carmen Vroonen
Global Head of Communications & Public Affairs
+32 473 824 874

Anna Gibbins
Senior Director Therapeutic Areas Communications
+44 7717 801900
communications@glpg.com

Forward-looking statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are subject to risks, uncertainties and other factors that could cause actual results to differ materially from those referred to in the forward-looking statements and, therefore, the reader should not place undue reliance on them. These risks, uncertainties and other factors include, without limitation, the risk that ongoing and future clinical studies with GLPG3970 may not be completed in the currently envisaged timelines or at all, the inherent uncertainties associated with competitive developments, clinical trial and product development activities and regulatory approval requirements (including that data from the ongoing and planned clinical research programs may not support registration or further development of GLPG3970 due to safety, efficacy or other reasons), Galapagos' reliance on collaborations with third parties and that Galapagos' estimations regarding its GLPG3970 development program and regarding the commercial potential of GLPG3970, may be incorrect, as well as those risks and uncertainties identified in our Annual Report on Form 20-F for the year ended 31 December 2019 and our subsequent filings with the SEC. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The forward-looking statements contained herein are based on management's current expectations and beliefs and speak only as of the date hereof, and Galapagos makes no commitment to update or publicly release any revisions to forward-looking statements in order to reflect new information or subsequent events, circumstances or changes in expectations.